510(K) SUMMARY OF SAFETY & EFFECTIVENESS

Official Contact	Zita A. Yurko Manager, Regulatory Affairs/Product Assurance Respironics, Inc. 1001 Murry Ridge Lane Murrysville, PA 15668
Classification Reference	21 CFR 868.5450
Product Code	Respiratory gas humidifier (BTT)
Common/Usual Name	HUMIDIFIER, RESPIRATORY GAS, (DIRECT PATIENT INTERFACE)
Proprietary Name	Respironics Heated Humidifier
Predicate Device(s)	Respironics REMstar Plus CPAP System/REMstar Heated Humidifier (K010263) Fisher & Paykel, HC100 Respiratory Humidifier (K915460)
Reason for submission	New design.

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92:

(a)(1) – (a)(3) Refer to information above and concluding this summary

(a)(4) Description of the Device

The Respironics Heated Humidifier is a Respiratory Gas Humidifier (heated Passover type) according to 21 CFR 868.5450. Heat is used to provide an evaporated water content to dry breathing gases.

The Respironics Heated Humidifier has a thermoplastic enclosure with dimensions of 5.5 in. high x 6.5 in. wide x 5.25 in. deep and weighs 1.24 lbs. (without the chamber fitted), 1.63 lbs. (with the chamber fitted), and 2.5 lbs. (with the chamber fitted and filled with water). The unit is compromised of a metal heater plate that is controlled from control electronics, contained in a plastic enclosure that is directly supplied with AC power. The heater plate is positioned in the front of the unit. The humidification chamber slides onto the heater plate and is held in place by a rim on the enclosure. The unit controls are located on the top panel.

Accessories for the Respironics Heated Humidifier include humidification chambers, breathing tubing and mounting arrangements.

(a)(5) Statement of the Intended Use

The Respironics Heated Humidifier is intended to warm and add moisture to the breathing gases for administration to a patient. It is used for patients who use mask-applied CPAP or Bi-level therapy for the treatment of Obstructive Sleep Apnea. The addition of heated humidification to this therapy relieves the drying and irritating effects on the patient airways, which may arise from use of a CPAP or Bi-level system.

(a)(6) Technological Characteristics Summary

The technological characteristics of the Respironics Heated Humidifier are equivalent to the Fisher & Paykel HC100 humidifier predicate device listed above.

The Respironics Heated Humidifier is equivalent in terms of: type (heated Passover humidification) configuration (chamber, breathing tubing, physical design, user controls, energy delivered, humidifier design concept, inlet port and outlet port sizing). Differences from the predicate device include: weight, size, energy type, user controls (5 settings vs. 9 settings), temperature range (off to 65°C vs. 47 to 65°C) and delivered humidity.

(b)(1) Discussion of the Non-Clinical Tests

Non-clinical testing of the Respironics Heated Humidifier has been carried out covering mechanical, electrical and thermal safety, environmental conditions and electromagnetic compatibility, functional verification, software verification, system validation and performance.

The Respironics Heated Humidifier meets the requirements of the IEC 60601-1 Medical Electrical Equipment Part 1: General Requirements for safety and the relevant USA deviations in UL 2601-1.

(b)(2) Discussion of the Clinical Tests

Clinical verification studies on the Respironics Heated Humidifier were not required in order to demonstrate safety, effectiveness and performance of the device.

(b)(3) Conclusions Demonstrating Safety, Effectiveness of Performance

The testing carried out for the Respironics Heated Humidifier indicates that it meets design and performance functional requirements. The proposed device meets the requirements of international and USA medical electrical equipment standards for safety, and key performance and safety requirements from particular standards for humidification systems.

This information indicates that the Respironics Heated Humidifier is equivalent to the predicate device in terms of safety, effectiveness and performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 8 2002

Mr. David J. Vanella
Respironics, Inc.
1001 Murry Ridge Lane
Murrysville, PA 15668

Re: K012633
Respironics Heated Humidifier
Regulation Number: 868.5450
Regulation Name: Respiratory Gas Humidifier
Regulatory Class: II (two)
Product Code: BTT
Dated: February 7, 2002
Received: February 8, 2002

Dear Mr. Vanella:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

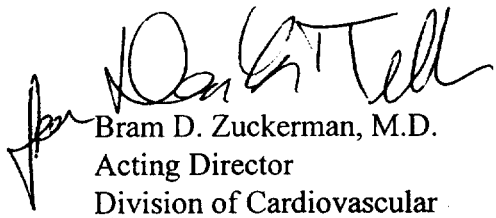
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K012633

Device Name: Respironics Heated Humidifier

Intended Use/Indications for Use

The Respironics Heated Humidifier is an accessory for CPAP and Bi-level systems to provide moisture to the patient circuit.

Environment of Use/Patient Population

It is intended for use with adult patients, in the home or hospital/institutional environment, who use mask-applied CPAP or Bi-level therapy for the treatment of Obstructive Sleep Apnea.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use

(Per 21 CFR 801.109) (Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices

510(k) Number K012633